



K043307

510(k) Summary

DEC 17 2004

Date

November 26, 2004

Submitters Information

Soredex Instrumentarium Corporation

Nahkelantie 160

FIN-04300 Tuusula

Finland

Phone: +358 10 394820

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Contact: Kai Lanér

Trade Name

Cranex D

Common Name

Dental panoramic x-ray equipment, digital, upgradeable for cephalometric radiography

Classification

Unit, x-ray, extraoral, with timer / EHD

Predicate Device

We consider that Cranex D is substantially equivalent in design, composition and function with Orthophos DS / DS Ceph (K972312) and with Cranex Basex D or Cranex Excel D (K040382).

Product Description

Cranex D is a panoramic extraoral source dental x-ray system, which produces digital images of dentition. The device is upgradeable for cephalometric radiography. Cranex D utilizes digital image receptor (CCD).

The technique factor settings for panoramic examinations are: 57 – 85 kVp, 10 mA DC and 17.6 s max. The technique factor settings for cephalometric radiographs are: 60 – 85 kVp, 10 mA DC and 8 – 20 s.

Intended Use

The Cranex D dental panoramic equipment is indicated for dental radiographic examinations by producing digital radiographs of dentition, TM-joints and other oral structures. The Cranex D is upgradeable for cephalometric radiography and examinations related thereto.

Performance data

Verification and validation testing was successfully performed to confirm that Cranex D corresponds with the intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Mr. Kai Lanér
Soredex Instrumentarium Corporation
Nahkelantie 160
FIN 00430 Tuusula
FINLAND

Re: K043307
Trade/Device Name: Cranex D
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source
x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: November 26, 2004
Received: December 1, 2004

Dear Mr. Lanér:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

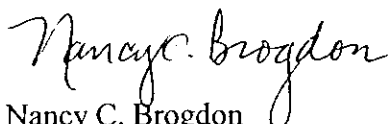
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER : K043307

DEVICE NAME : Cranex D

INDICATIONS FOR USE :

The Cranex D dental panoramic equipment is indicated for dental radiographic examinations by producing digital radiographs of dentition, TM-joints and other oral structures. The Cranex D is upgradeable for cephalometric radiography and examinations related thereto.

Prescription Use _____



David A. Seppala
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043307